

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Display Date	6-7-01
Publication Date	6-8-01
Certifier	<i>[Signature]</i>

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 26 and 27, 2001, 8 a.m. to 5 p.m.

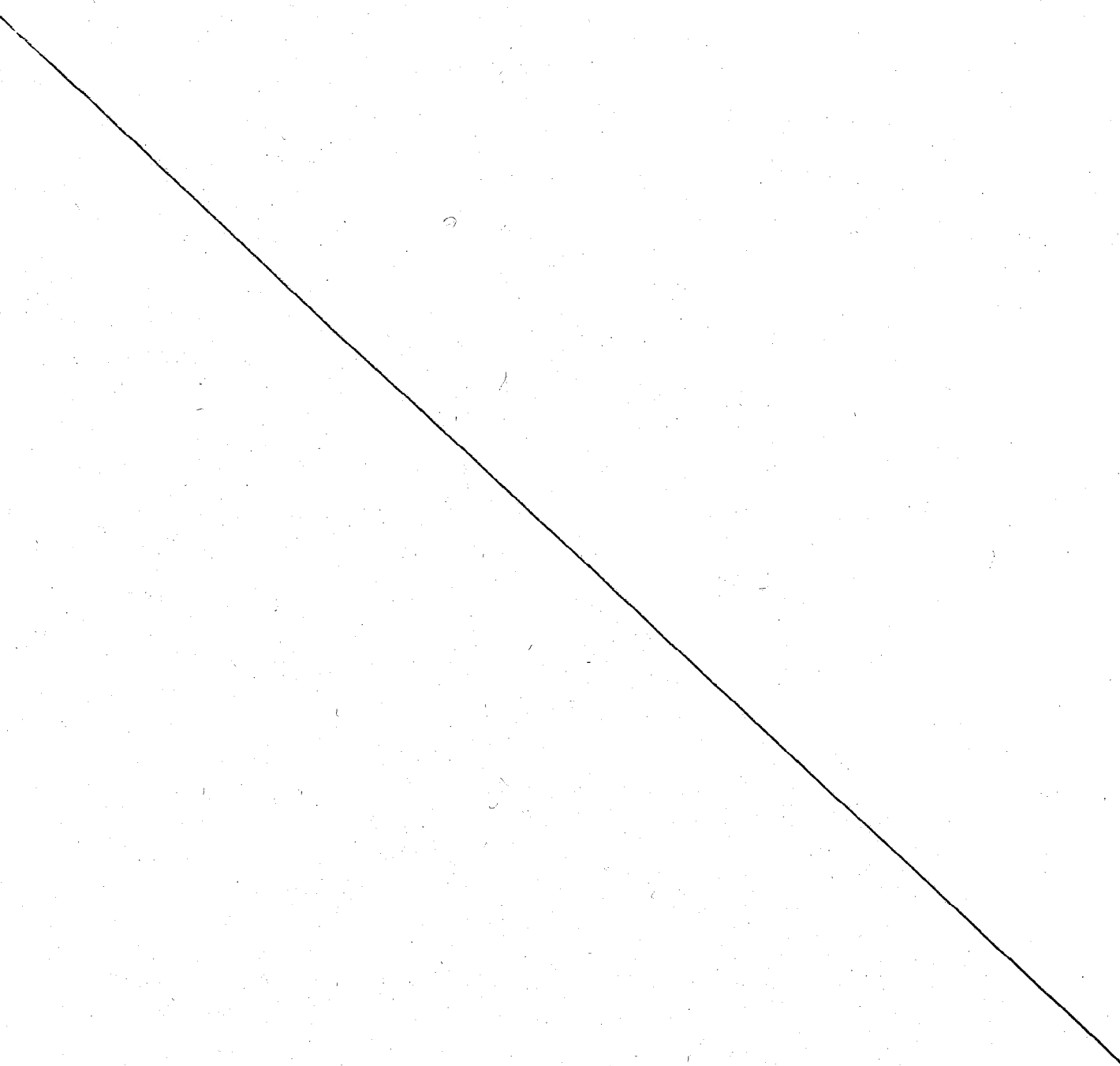
Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX 301-827-6776, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 26, 2001, the committee will discuss new drug application (NDA) 21-332, Symlin™ (pramlintide acetate, Amylin Pharmaceuticals, Inc.) as an adjunctive therapy to insulin to improve glycemic and metabolic control in patients with type 1 or type 2 diabetes mellitus alone or in combination with oral hypoglycemic agents. On July 27, 2001, the committee will discuss NDA 21-318, Fortéo™ (teriparatide injection, rDNA origin, Eli Lilly and Co.) for the treatment of osteoporosis in men and in postmenopausal women.

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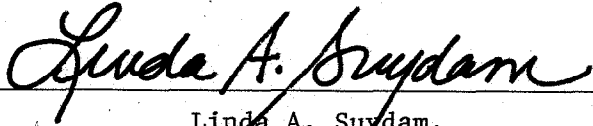
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 20, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 20, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

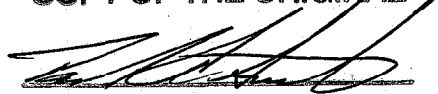
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Dated: 5/31/01
May 31, 2001.



Linda A. Suydam,
Senior Associate Commissioner.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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